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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

March 6, 2018

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining U.S. Public Health Preparedness for and Response Efforts to Seasonal Influenza"

On **Thursday, March 8, at 10:00 a.m. in room 2123 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Examining U.S. Public Health Preparedness for and Response Efforts to Seasonal Influenza."

I. BACKGROUND

Influenza, or the flu, is "a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and sometimes the lungs."[1] While typical symptoms include fever, cough, or sore throat, complications from the flu can lead to increased susceptibility to severe illnesses like bacterial pneumonia or even death. The duration of flu season varies, but it can begin in October and last as late as May. Peak activity generally occurs between December and March.[2]

According to the Centers for Disease Control and Prevention (CDC), "the single best way to protect against the flu is to get vaccinated each year."[3] For this reason, CDC recommends that

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[1] Centers for Disease Control and Prevention, *Key Facts about Influenza (Flu) and Flu Vaccine* (www.cdc.gov/flu/keyfacts.htm).

[2] Centers for Disease Control and Prevention, *The Flu Season* (www.cdc.gov/flu/about/season/flu-season.htm).

[3] Centers for Disease Control and Prevention, *Key Facts about Seasonal Flu Vaccine* (www.cdc.gov/flu/protect/keyfacts.htm).

everyone over six months of age get a flu vaccine every season. Preliminary estimates indicate that approximately 40 percent of children and adults received the flu vaccine this year,[4] that the vaccine reduced the risk of infection by 36 percent in the general population, and that it was approximately 59 percent effective in children between the ages of 6 months and 8 years.[5] The flu vaccine typically reduces an individual's risk of becoming infected with the flu by 40 to 60 percent.[6]

Even in years of reduced vaccine effectiveness, the flu vaccine is associated with a decreased risk of death and less severe symptoms for those who do become infected. For example, during the 2014-15 flu season, vaccine effectiveness was less than 20 percent, but CDC estimates that vaccination still prevented almost 50,000 influenza-associated hospitalizations and nearly 1,500 influenza-associated deaths.[7] This year, CDC estimates that around 75 percent of the children who died due to flu were not vaccinated.[8]

II. 2017-2018 FLU SEASON

The current influenza season has been among the worst since the H1N1 "swine flu" epidemic of 2009-2010.[9] As of March 2, 2018, the flu had caused the deaths of 114 children, and led to 81.7 hospitalizations for every 100,000 people.[10] During the week of February 4, the proportion of deaths attributable to influenza and influenza-associated pneumonia was 10.1 percent, meaning that one out of every ten deaths that week was caused by these illnesses.[11]

The severity of this flu season is due largely to one strain of the illness, H3N2, a form of

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[4] Centers for Disease Control and Prevention, *National Early-Season Flu Vaccination Coverage, United States, November 2017* (/www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2017.htm).

[5] Centers for Disease Control and Prevention, *Interim Estimates of 2017-18 Seasonal Influenza Vaccine Effectiveness – United States, February 2018* (http://dx.doi.org/10.15585/mmwr.mm6706a2).

[6] Centers for Disease Control and Prevention, *Vaccine Effectiveness – How Well Does the Flu Vaccine Work?* (www.cdc.gov/flu/about/qa/vaccineeffect.htm).

[7] Centers for Disease Control and Prevention, *Estimated Influenza Illnesses, Medical Visits, Hospitalizations, and Deaths Averted by Vaccination in the United States* (www.cdc.gov/flu/about/disease/2015-16.htm).

[8] Centers for Disease Control and Prevention, Teleconference with Committee staff, March 1, 2018.

[9] *This Flu Season Has Now Reached Pandemic Levels (But It's Not Technically a Pandemic),* Washington Post (Feb. 9, 2018).

[10] Centers for Disease Control and Prevention, *Situation Update: Summary of Weekly FluView Report* (www.cdc.gov/flu/weekly/summary.htm).

[11] Centers for Disease Control and Prevention, *CDC Update on Widespread Flu Activity* (www.cdc.gov/media/releases/2018/t0209-flu-update-activity.html).

the influenza A virus described as particularly problematic.[12] H3N2-dominant years typically result in more severe illness and mortality, especially in older people and young children, than years where other strains have dominated.[13] H3N2 years also tend to see twice as many hospitalizations and deaths than other years.

III. ADVANCES IN PREVENTING AND TREATING THE FLU

The flu vaccine is manufactured using live viruses, which are traditionally grown in hens' eggs before being killed or weakened and put into vials or syringes.[14] There are some indications that this year, flu vaccines manufactured with a newer technology that uses cultured animal cells, rather than hens' eggs, to grow the viruses, actually provided greater protection from flu infection.[15] Increasing manufacturers' capacity to grow vaccines using this cell-based process or another new process which uses recombinant protein technology may result in more effective vaccines in the future.

Because influenza viruses tend to rapidly mutate and change, the flu vaccine must be reformulated every year to protect against the strains of flu most likely to cause infection in the upcoming season.[16] On February 28 of this year, the National Institute of Allergies and Infectious Diseases announced a new initiative to develop a universal influenza vaccine which would target all influenza type-A virus strains and would therefore offer more broadly protective immunity.[17]

For those who become infected, CDC recommends taking antiviral drugs within the first 24 hours of symptoms to reduce the length and severity of the illness.[18] There are currently a number of new antiviral drugs under investigation which may help clinicians treat flu victims more quickly, including one which claims to kill the virus within one day.[19]

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[12] *'The Problem Child of Seasonal Flu': Beware This Winter's Virus*, Stat News (Jan. 8, 2018) (www.statnews.com/2018/01/08/flu-virus-h3n2/).

[13] *Id.*

[14] Food and Drug Administration, *The Evolution, and Revolution, Of Flu Vaccines* (www.fda.gov/ForConsumers/ConsumerUpdates/ucm336267.htm).

[15] Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D. on the efficacy of the 2017-18 influenza vaccine* (Feb. 15, 2018) (press release).

[16] LiveScience, *Flu Shot Facts & Side Effects (Updated for 2017-2018)* (www.livescience.com/40279-flu-shot-information.html).

[17] *A Universal Flu Vaccine May Be on the Horizon*, Smithsonian Magazine (Jan. 26, 2015) (www.smithsonianmag.com/science-nature/measles-vaccine-universal-flu-influenza-cdc-disease-outbreak-180954020/?no-ist).

[18] Centers for Disease Control and Prevention, *What You Should Know about Flu Antiviral Drugs* (www.cdc.gov/flu/antivirals/whatyoushould.htm).

[19] *Japan Just Approved a New Drug That Can kill the Flu Virus in Just One Day*, Fortune (Feb. 23, 2018).

IV. AGENCY RESPONSIBILITIES

CDC operates the U.S. seasonal flu surveillance systems, which track trends in the rate of illness and hospitalization.[20] CDC also monitors the types and subtypes of circulating flu viruses, the emergence of new strains, and the geographic spread of the flu virus. Additionally, CDC administers two programs, the Section 317 Immunization Program and the Vaccines for Children program, which provide vaccines to uninsured and underinsured children, adolescents, and adults and invests in the infrastructure necessary to reach these populations.[21] Finally, CDC currently maintains the Strategic National Stockpile (SNS), the nation's repository of flu vaccines and other critical pharmaceutical products and medical supplies for use during a public health emergency. The Fiscal Year 2019 President's budget request includes a proposal that the Administration has begun implementing to shift SNS administration from CDC to the Assistant Secretary of Preparedness and Response.

FDA is "responsible for the licensure and regulation of influenza vaccine — including the approval of facilities in which influenza vaccine is produced — for the U.S. market."[22] FDA issues guidance, consults with manufacturers, and regulates the vaccine's production and use. FDA also reviews and approves the composition of the seasonal vaccine annually.[23]

The Biomedical Advanced Research and Development Authority (BARDA), located within the Office of the Assistant Secretary for Preparedness and Response (ASPR), contracts with vaccine manufacturers for advanced research and development for vaccine technologies to respond to public health emergencies.[24] The National Institutes of Health (NIH) conducts research to prevent, diagnose, and treat seasonal and pandemic influenza.[25]

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[20] Centers for Disease Control and Prevention, *Overview of Influenza Surveillance in the United States* (www.cdc.gov/flu/weekly/overview.htm).

[21] Centers for Disease Control and Prevention, *Justification of Estimates for Appropriations Committees* (Fiscal Year 2018) (www.cdc.gov/budget/documents/fy2018/fy-2018-cdc-congressional-justification.pdf).

[22] Government Accountability Office, *Influenza Vaccine: Federal Investments in Alternative Technologies and Challenges to Development and Licensure* (June 2011) (GAO-11-435).

[23] Food and Drug Administration, *Vaccines and Related Biological Products Advisory Committee* (www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/).

[24] Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, *Influenza Division* (www.phe.gov/about/barda/Pages/influenza.aspx).

[25] National Institute of Allergy and Infectious Diseases, National Institutes of Health, *NIAID Role in Influenza Research* (www.niaid.nih.gov/topics/flu/Pages/default.aspx).

V. WITNESSES

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